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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,577	12/05/2003	Scott A. Burton	57260US003	8901

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/728,577	BURTON ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-26,60,71 and 74-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-26,60,71 and 74-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/18/08 & 2/21/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of IDS filed 2/21/2008 and 3/18/2008, request for continued examination under 37 CFR 1.114, amendment and remarks filed 2/21/2008. Claims 1, 54 and 55 are cancelled. Claims 2-6, 60, 71 and 74-76 are amended. Claims 2-26, 60, 71 and 74-76 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/21/08 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-17, 20-23, 71 and 74-76 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorenzi et al. (US 6,217,889).

Lorenzi discloses compositions comprising synthetic polymer such as polyamides, polyurethane foam and polyesters (column 4, lines 49-64), which is constituent of the creped non-woven layer of the composition in the form of film or sponges (column 4, lines 12,13; column 6, lines 48-51; column 8, lines 37-40) and meeting claims 71, 2, 7-12, 16, 20, 21; therapeutic agents such as silver nitrate antiviral agents (column 31, line 64) or zinc oxide sunscreen actives (column 32, lines 28 and 29) meeting claim 71 and silver nitrate, a silver compound that meets the requirement that the solubility of the silver compound in water is at least 0.1 gram per liter; composition may also contain cationic lathering surfactants (column 14, lines 32-46) meeting claims 13 and 14; the composition may also contain dyes or preservatives (Example 8) and silicone antifoaming agent (column 24, line 1) meet the requirements of claim 15. The emulsion of Lorenzi is an inverse emulsion (column 23, lines 45 and 46). Combinations of polymers are contemplated (column 4, lines 54) meet claim 17. Lorenzi suggests that polymeric gelling agents in the form of particles can be used (column 35, lines 21-

23 and 28) meeting the particle requirement of claim 1. The recitation of wound dressing is the intended use of the composition so that Lorenzi meets the wound dressing limitation of the amended claims. The solubility parameter recited in claim 71 for the silver compound is inherent to the silver compound as stated above because a compound and its properties are not separable. Regarding claim 74 where the microparticles comprise polyquaternary amine containing compound, it is noted that Lorenz teaches the presence of quaternary amine compounds (column 14, line 33 to column 16, line 61) and also polyquaternium compounds (column 24, lines 27-65). Regarding claims 75 and 76 and the amounts of the bioactive agent, it is within the technical grasp of the artisan to use amounts of the bioactive agents that would produce the desired effects. Regarding the non-adherent nature of the composition of amended claim 71, it is noted that non-adherence is a property of the composition and the composition of Lorenz would inherently be non- adherent.

Claim 71 is a product by process claim. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the present case, the claims are directed to a product and patentability of the claims is not dependent on how the product is made.

In the alternative, however, regarding the microparticles, it is noted that there is no demonstration in applicant's specification that the particle size of 10 microns or less provides unexpected results.

Therefore, taking the teaching of Lorenz, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that the emulsion of Lorenz would contain particles and in the absence of factual showing, the particle size recited in the claims would not patentably distinguish the claimed invention over Lorenzi.

Response to Arguments

5. Applicant's arguments filed 2/21/08 have been fully considered but they are not persuasive.

Applicant argues that claim 71, which was not rejected over Lorenzi and claim 74 that has been amended to include the limitations of claim 1 so that applicant says that applicant does not agree with the rejection over Lorenzi. The examiner disagrees. Lorenzi describes the claimed invention and claim 71 was inadvertently omitted in the previous rejections because the composition of Lorenzi is non-adherent since Lorenzi does not say that the composition is adherent and also because the product is used as a cleansing non-woven material.

6. Claims 2-26, 60, 71 and 74-76 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Asmus (US 5,270,358).

Asmus discloses a composite (column 40, lines 16-45) as a wound care product (column 44, lines 17-30) meeting claims 60 and 71; the composite contains a gel at 1-95 wt % and having a size of 1-600 microns (column 19, lines 16-20) with the particle size encompassing the claimed particle size of 10 micron or less in claims 1-5; the composite also contains hydrocolloid (column 6, line 54 to column 8, line 50) meeting limitation of a hydrophilic polymer and a swelling agent; the composite composition contains antimicrobial agents such as silver oxide and silver salts (column 12, lines 27-44) meeting the requirement for bioactive agent and silver

compound of claims 71 and 74; the pressure sensitive adhesive (column 4, lines 53 to column 6, line 29) meeting the limitation of matrix polymer of claim 1; the presence of water (column 9, lines 66-67) meets claim 26; tackifiers and crosslinkers and stabilizers (column 6, lines 3) meet claim 15. The solubility parameter recited in claims 71 and 74 for the silver compound is inherent to the silver compound because a compound and its properties are not separable. Claim 71 and 74 are product by process claims and patentability of the claim is based on the product and not on the manipulations of the process steps. Regarding claim 75, it is within the technical grasp of the artisan to use amounts of the bioactive agents that would produce the desired effects. In the alternate, the particle size of Asmus renders obvious the recited particle size since the disclosed particle size overlaps the recited particle size.

Response to Arguments

7. Applicant's arguments filed 2/21/08 have been fully considered but they are not persuasive.

Applicant argues that a) not all silver salts have a solubility of at least 0.1 gram/liter and according to the 64th edition of the CRC handbook at page B-137 provided as exhibit A and specifically mentions silver oxide having a solubility of 0.013 gram/liter in cold water and 0.053 gram/liter in hot water, and silver sulfate having solubility of at least 0.1 gram/liter, and silver stearate having solubility of 0.06 gram/liter; that Asmus generically lists "silver oxide, and silver and its salts" as antimicrobial agents; that there is no disclosure in Asmus for copper or zinc compounds or combinations thereof. The examiner disagrees. First of all, the rejection is not based upon the presence of copper or zinc compounds in Asmus, secondly, the bioactive agent is one of silver compound, zinc compound or copper compound and the prior art only has to teach

one of the members of the group recited. Regarding the solubility of silver compounds, the examiner agrees that not all silver compounds are equally soluble and claims 71 and 74 recite a broad category of silver compound that has the recited solubility. The prior art states that silver salts are used as antimicrobial agent. The CRC reference previously submitted by applicant lists silver nitrate to have a solubility of 122 grams/100 in cold water and that is at least 0.1 gram/liter. Silver nitrate is a silver salt so that while the solubility is a property of the compound, the silver salt of Lorenzi would also have that solubility when the salt is silver nitrate. Furthermore, silver acetate (solubility of about 10 gram/liter in cold water), silver bromated (1.9 gram/liter in cold water), are all silver compounds having solubility of at least 1 gram/liter.

b) Applicant argues that there is no teaching or suggestion that one of skill in the art would be guided to select such bioactive agents and combine them with other components in a manner to produce a polymer mixture comprising organic polymer matrix and the microparticles comprising an amine containing organic polymer. The examiner disagrees because as noted by the applicant Asmus teaches the presence of silver salt in the composition and silver salt is a silver compound. Product by process claims are not limited to the manipulations of the steps, but to the structure implied by the steps. In this case, Asmus teaches the product.

c) Applicant argues that Asmus does not suggest non-adherent composition and that applicant's specification at page 4, lines 3-10 says that the polymer composition is non-adherent to steel and preferably to wound tissue. The examiner disagrees. The claims are directed to a product and the composition being non-adherent is the characteristic/property of the composition and the composition of Asmus having the same polymers would also be non-adherent. Applicant says that the composition is non-adherent to steel and wound tissue, which is also the

characteristic of the composition. It is further noted that, though adherence of non-adherence is a characteristic of the composition, the claims have not indicated what the surface is that the composition does not adhere to. It is further noted that applicant has not provided a showing that the composition of Asmus adheres to steel or skin or wound.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 2-26, 60, 71 and 74-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 12-51, 53-55, 58-93; 1-44 of copending Application Nos. 10/728,439; 10/728,446. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims and the co-pending claims are directed to composition that contains bioactive silver compounds, polymer matrix, foaming agent and the composition is used as care for wounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 2-26, 60, 71 and 74-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/729,114 in view of Asmus (5,270,358). The copending application discloses the composition of the examined claims except that the claims are silent as to whether the composition is an emulsion or not. However, Asmus discloses an emulsion that comprises the composition of the copending application for use in wound care. Therefore, it would have been obvious to use the composition of the co-pending application as an emulsion in wound treatment.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

11. Applicant's arguments filed 2/21/08 have been fully considered but they are not persuasive.

Applicant proposes to address the provisional obviousness-type double patenting rejection when allowable subject matter is identified. However, the rejection is maintained.

Information Disclosure Statement

12. The information disclosure statement filed 2/21/08 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because applicant has not provided the Foreign and non-patent literature references. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of

determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618